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ATTY DOCKET NO. P-CJ 1192

SERIAL NO. 08/328,673

APPLICANT Gregory et al.

INFORMATION DISCLOSURE 7 STATEMENT BY APPLICANT 199

FILING DATE 10/25/94

GROUP 1806 /636

## U.S. PATENT DOCUMENTS

· EXAM. INITIALS	-	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE

## FOREIGN PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

BW		Aiello et al. "Adenovirus 5 DNA Sequences Present and RNA Sequences Transcribed in Transformed Human Embryo Kidney Cells (HEK-Ad-5 or 293) <u>Virology</u> 94:460-469 (1979).
BW	<i>ب</i>	Aulitzky et al. "Recombinant Tumour Necrosis Factor Alpha Administered Subcutaneously or Intramuscularly for Treatment of Advanced Malignant Disease: Phase I Trial." <u>Eur. J. Cancer</u> 27(4):462-467 (1991).
BM		Austin, E.A. and Huber, B.E. "A First Step in the Development of Gene Therapy for Colorectal Carcinoma: Cloning, Sequencing, and Expression of <i>Escherichia coli</i> Cytosine Deaminase." <u>Eur. J. Cancer</u> 27(4):462-467 (1991).
BM	٠	Bacchetti, S. and Graham, F. "Inhibition of cell proliferation by an adenovirus vector expressing the human wild type p53 protein." <u>International Journal of Oncology</u> 3:781-788 (1993).
BH		Baker et al. "Suppression of Human Colrectal Carcinoma Cell Growth by Wild- Type p53." 249:912-915 (1990).
BW		Bartek et al. "Aberrant expression of the p53 oncoprotein is a common feature of a wide spectrum of human malignancies." <u>Oncogene</u> 6:1699-1703 (1991).
BW		Berkner, Kathleen L. and Sharp, Phillip A. "Effect of the tripartite leader on synthesis of a non-viral protein in an adenovirus 5 recombinant." <u>Nucleic</u> <u>Acids Research</u> 13(3):841-857 (1985).
BH		Boshart et al. "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus." <u>Cell</u> 41:521-530 (1985).
BW		Bressac et al. "Abnormal structure and expression of p53 gene in human hepatocellular carcinoma." <u>Proc. Natl. Acad. Sci. (USA)</u> 87:1973-1977 (1990).
BW		Caruso et al. "Regression of established macroscopic liver metastases after in situ transfduction of a suicide gene." <a href="Proc.Natl.Acad.Sci. (USA)">Proc. Natl. Acad. Sci. (USA)</a> 90:7024-7028 (1993).

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

FILING DATE 10/25/94

GROUP 1806 /636

BW		Challberg, M.D. and Kelly, T.J. <u>PNAS USA</u> , 76:655-659 (1979).
BN		Chen et al. "Genetic Mechanisms of Tumor Suppression by the Human p53 Gene." <u>Science</u> 250:1576-1580 (1990).
BW	_	Chen et al. "Expression of wild-type p53 in human A673 cells suppresses tumorigenicity but not growth rate." Oncogene 6:1799-1805 (1991).
BW		Cheng et al. "Suppression of Acute Lymphoblastic Leukemia by the Human Wild- Type p53 Gene." <u>Cancer Research</u> 52:222-226 (1992).
BW		Colby, W.W. and Shenk, T.J., "Adenovirus Type 5 Virions Can be Assembled in Vivo in the Absence of Detectable Polypeptide IX" <u>Virology</u> 39:977-980 (1981)
BH		Culver et al. "In Vivo Gene Transfer with Retroviral Vector-Producer Cells for Treatment of Experimental Brain Tumors" <u>Science</u> 256:1550-1552 (1992).
BW	, /	Culver et al. "Lymphocytes as a cellular vehicles for gene therapy in mouse and man." Proc. Natl. Acad. Sci. USA 88:3155-3159 (1991).
BW		Demetri et al. "A Phase I Trial of Recombinant Human Tumor Necrosis Factor and Interferon-Gamma: Effects of Combination Cytokine Administration In Vivo." <u>J.</u> <u>Clin. Oncol.</u> 7(10):1545-1553.
BW		Diller et al. "p53 Functions as a Cell Cycle Control Protein in Osteosarcomas."  Mol. Cell. Biology 10:5772-5781 (1990).
BW		El-Deiry et al. "WAF1, a Potential Mediator of p53 Tumor Suppression." <u>Cell</u> 75:817-825 (1993).
BW		Ezzidine et al. "Selective Killing of Glioma Cells in Culture and in Vivo by Retrovirus Transfer of the Herpes Simplex Virus Thymidine Kinase Gene." <u>The</u> <u>New Biologist</u> 3:608-614 (1991).
BW		Feinstein et al. "Expression of the normal p53 gene induces differentiation of K562 cells." Oncogene 7:1853-1857 (1992).
BHP		Freeman et al. "The "Bystander Effect": Tumor Regression When a Fraction of the Tumor Mass Is Genetically Modified." <u>Cancer Res.</u> 53:5274-5283 (1993).
BM		Ghosh-Choudhury et al. "Protein IX, a minor component of the human adenovirus capsid, is essential for the packaging of full length genomes." <u>EMBO Journal</u> 6:1733-1739 (1987).
BN	,	Gooding et al. "Molecular Mechanisms by Which Adenoviruses Counteract Antiviral Immune Defenses." <u>Crit. Rev. Immunol.</u> 10:53-71 (1990).
BM		Graham, F.L. and van der Eb, A.J. "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA." <u>Virology</u> 52:456-467 (1973).
THE		Graham, F L and Prevec, L. Vaccines: New Approaches to Immunological
<del>/ ` \</del>	21.6	- <u>Problems</u> . R.W. Ellis (ed.), Boston: Butterworth-Heinemann, 363-390 (1992).

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FORM PTO-1449 US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO. P-CJ 1192	SERIAL NO. 08/328,673
	APPLICANT Gregory et al.	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE 10/25/94	GROUP 1805 /6 3 6

Brr	Heuvel et al. "Association between the cellular p53 and the adenovirus 5 E1B-55kd proteins reduces the oncogenicity of Ad-transformed cells." EMBO Journal 9:2621-2629 (1990).
BW	Hock et al. "Mechanisms of rejection induced by tumor cell-targeted gene transfer of interleukin 2, interleukin 4, interleukin 7, tumor necrosis factor, or interferon γ." Proc. Natl. Acad. Sci. USA 90:2774-2778 (1992).
BIV	Hollstein et al. "p53 Mutations in Human Cancers." Science 253:49-53 (1991).
BW	Horwitz, Marshall S. "Adenoviridae and Their Replication." <u>sVirology</u> B.N. Fields (ed.), New York: Raven Press, 1679-1721 (1990).
BM	Horvath, J. and Weber, J.M. "Nonpermissivity of Human Peripheral Blood Lymphocytes to Adenovirus Type 2 Infection." <u>J. Virol.</u> 62:341-345 (1988).
BW	Huang et al. "A cellular protein that competes with SV40 T antigen for binding to the retinoblastoma gene product." Nature 350:160-162 (1991).
BW	Huber et al. "Retroviral-mediated gene therapy for the treatment of hepatocellular carcinoma: An innovative approach for cancer therapy." <a href="Proc.Natl.Acad.Sci.USA">Proc.Natl.Acad.Sci.USA</a> 88:8039-8043 (1991).
BW	Hunter, T. "Braking the Cycle." <u>Cell</u> 75:839-841 (1993).
BIN	Jones, N. and Shenk, T. "Isolation of Adenovirus Type 5 Host Range Deletion Mutants Defective for Transformation of Rat Embryo Cells." Cell 17:683-689 (1979).
BW	Kamb et al. "A Cell Cycle Regulator Potentially Involved in Genesis of Many Tumor Types." <u>Science</u> 264:436-440 (1994).
BW	Kuerbitz et al. "Wild-type p53 is a cell cycle checkpoint determinant following irradiation." <u>Proc. Natl. Acad. Sci. USA</u> 89:7491-7495 (1992).
BN	Landmann et al. "Prolonged Interferon-γ Application by Subcutaneous Infusion in Cancer Patients: Differential Response of Serum CD14, Neopterin, and Monocyte HLA Class I and II Antigens." J. Interferon Res. 12(2):103-111 (1992).
BN	Lane, D.P. "p53, guardian of the genome." <u>Nature</u> 358:15-16 (1992).
BW	Lee et al. "Human Retinoblastoma Susceptibility Gene: Cloning, Identification, and Sequence." <u>Science</u> 235:1394-1399 (1987).
Bh	Lemaistre et al. "Therapeutic effects of genetically engineered toxin (DAB <sub>486</sub> IL-2) in patient with chronic lymphocytic leukaemia." <u>Lancet</u> 337:1124-1125 (1991).

•	FORM PTO-1449 US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO. P-CJ 1192	SERIAL NO. 08/328,673
		APPLICANT Gregory et al.	
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE 10/25/94	GROUP 1806/636

BN		Lemarchand, Patricia. "Adenovirus-mediated transfer of a recombinant human $\alpha_1$ -antitrypsin cDNA to human endothelial cells." <u>Proc. Natl. Acad. Sci. USA</u> 89:6482-6486 (1992).
BW	(	Levine, A.J. "The Tumor Suppressor Genes." <u>Annu. Rev. Biochem.</u> 62:623-651 (1993).
BN	1	Lowe et al. "p53 is required for radiation-induced apoptosis in mouse thymocytes." <u>Nature</u> 362:847-852 (1993).
BW		Lowe et al. "p53-Dependent Apoptosis Modulates the Cytotoxicity of Anticancer Agents." <u>Cell</u> 74:957-967 (1993).
W	(	Mercer, et al. "Negative growth regulation in a glioblastoma tumor cell ine that conditionally expresses human wild-type p53." <u>Proc. Natl. Acad. Sci. USA</u> 87:6166-6170 (1990).
BW		Metzger, Gerard and Werbin, Harold. "Evidence for N-Acetoxy-N-2-acetylaminofluorene Induced Covalent-like Binding of Some Nonhistone Proteins to DNA in Chromatin." <u>Biochemistry</u> 18(4):655-659 (1979).
BW	,	Moolten, F.C. "Tumor Chemosensitivity Conferred by Inserted Herpes Thymidine Kinase Genes: Paradigm for a Prospective Cancer Control Strategy." <u>Cancer</u> <u>Res.</u> 46:5276-5281 (1986).
BM	1	Nakabayashi et al. "Transcriptional Regulation of α-Fetoprotein Expression by Dexamethasone in Human Hepatoma Cells." <u>The Journal of Biological Chemistry</u> 264:266-271 (1989).
BN	1	Palmer et al. "Genetically modified skin fibroblasts persist long after transplantation but gradually inactivate introduced genes." <u>Proc. Natl. Acad.</u>
BW		Rao et al. "The adenovirus E1A proteins induce apoptosis, which is inhibited by the E1B 19-kDa and Bcl-2 proteins." <a href="Proc.Natl.Acad.Sci.USA">Proc.Natl.Acad.Sci.USA</a> 89:7742-7746 (1992).
BW		Ravoet et al. "Non-Surgical Treatment of Hepatocarcinoma." <u>Journal of Surgical</u> Oncology Supplement 3:104-111 (1993).
W		Rich et al. "Development and Analysis of Recombinant Adenoviruses for Gene Therapy of cystic Fibrosis." <u>Human Gene Therapy</u> 4:461-476 (1993).
BM		Rosenfeld et al. "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium." <u>Cell</u> 68:143-155 (1992).
BM	- ب	Sarnow et al. "Adenovirus E1b-58kd Tumor Antigen and SV40 Large Tumor Antigen Are Physically Associated with the Same 54 kd Cellular Protein in Transformed Cells." Cell 28:387-394 (1982).
BI		Shaw et al. "Induction of apoptosis by wild-type p53 in a human colon tumor-derived cell line." <u>Proc. Natl. Acad. Sci. USA</u> 89:4495-4499 (1992).

•	FORM PTO-1449	US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO. P-CJ 1192	SERIAL NO. 08/328,673
		Trademark Office	APPLICANT Gregory et al.	
	INFORMATION STATEMENT B		FILING DATE 10/25/94	GROUP 1806 /636

. BM	./	Siegfried, W. "Perspectives in Gene Therapy with Recombinant Adenoviruses." <u>Exp. Clin. Endocrinol.</u> 101:7-11 (1993).		
Bar		Sorscher et al. "Tumor cell bystander killing in colonic carcinoma utilizing the Escherichia coli DeoD gene to generate toxic purines." Gene Therapy 1:233-238.		
PM		Spector, David J. "The Pattern of Integration of Viral DNA Sequences in the Adenovirus 5-Transformed Human Cell Line 293." <u>Virology</u> 130:533-538 (1983).		
Bar		Stewart et al. "Difference imaging of adenovirus: bridging the resolution gap between X-ray crystallography and electron microscopy." <a href="EMBO Journal">EMBO Journal</a> 12:2589-2599 (1993).		
BN		Supersaxo et al. <u>Pharm. Res.</u> 5(8):472-476 (1988).		
BH	/	Straus, S.E. "Adenovirus infections in humans." <u>The Adenoviruses</u> . H.S. Ginsberg (ed.), New York: Plenum Press, 451-496 (1984).		
BW	/	Takahashi et al. "p53: A Frequent Target for Genetic Abnormalities in Lung Cancer." <u>Science</u> 246:491-494 (1989).		
Bhr		Takahashi et al. "Wild-type but not Mutant <i>p53</i> Suppresses the Growth of Human Lung Cancer Cells Bearing Multiple Genetic Lesions." <u>Cancer Research</u> 52:2340-2343 (1992).		
BW	_	Thimmappaya et al. "Adenovirus VAI RNA Is Required for Efficient Translation of Viral mRNAs at Late Times after Infection." <u>Cell</u> 31:543-551 (1982).		
BW	_	Wang et al. "Quantitation of mRNA by the polymerase chain reaction." <u>Proc.</u> Natl. Acad. Sci. USA 86:9717-9721 (1989).		
BW		Watanable et al. "Cell-specific Enhancer Activity in a Far Upstream Region of the Human α-Fetoprotein Gene." <u>The Journal of Biological Chemistry</u> 262:4812-4818 (1987).		
BW BW	_/	White et al. "The 19-Kilodalton Adenovirus E1B Transforming Protein Inhibits / Programmed Cell Death and Prevents Cytolysis by Tumor Necrosis Factor α." Mol. Cell. Biol. 12:2570-2580 (1992).		
BW	Į.	Wills et al. <u>Human Gene Therapy</u> 5:1079-1088 (1994).		
BW		Yonish-Rouach et al. "Wild-type p53 induces apoptosis of myeloid leukaemic cells that is inhibited by interleukin-6." Nature 352:345-347 (1991).		
EXAMINER	F	DATE CONSIDERED 4/4/96		

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